

# **FBI Laboratory Quality Assurance Manual Table of Contents**

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## **FBI Laboratory Quality Assurance Manual**

### **Introduction**

Quality performance is the most important goal of the FBI Laboratory. As new and improved methods of forensic analysis are developed to meet the expanding needs of the criminal justice system and intelligence matters, the laboratory quality system must progress in parallel. The FBI Laboratory is committed to diligently implementing policy and procedure changes to ensure quality in all facets of laboratory operations.

The FBI Laboratory quality system, represented by the Quality Assurance Manual, the Laboratory Operations Manual, and the unit, discipline and categories of testing documents, provides a mechanism for identifying and implementing the practices and procedures that support excellent performance. All FBI Laboratory personnel share responsibility for the overall success of the quality system by adhering to established quality measures.

The continued development and improvement of the FBI Laboratory quality system serves to increase confidence in the resulting work product while strengthening the professional integrity of the FBI Laboratory and its personnel. Through the use of recognized quality practices and procedures, the FBI Laboratory will continue to meet the challenges of future laboratory missions.

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## **1 Purpose**

This FBI Laboratory Quality Assurance Manual (QAM) contains or references the policies, practices, procedures, and accompanying forms of the FBI Laboratory quality system that ensure technical competence and valid forensic examination and DNA database results. The QAM and the FBI Laboratory Operations Manual (LOM) facilitate meeting the requirements of the applicable accrediting body(ies).

## **2 Scope**

The QAM and the LOM apply to FBI Laboratory personnel that could influence laboratory activities<sup>1</sup>. This includes personnel responsible for receiving, breaking down, handling, and examining evidence; DNA databasing; reviewing and issuing *Laboratory Reports* (7-1, 7-1 LIMS); providing instrument operations support; providing testimony in legal proceedings with respect to examinations conducted; and maintaining the quality system.

For terms used in this document and the LOM, refer to the LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual.

## **3 Quality Initiatives**

### **3.1 Forensic Examinations and Services**

Forensic examinations of evidence are performed in the FBI Laboratory to support FBI and other federal, state, local, and foreign investigations as well as intelligence matters. The FBI Laboratory also provides expert witness testimony. Additionally, FBI Laboratory personnel participate in ongoing field investigations by assisting with crime scene searches, providing DNA databasing services, as well as other scientific and/or technical services as necessary. The Handbook of Forensic Services contains a general listing of forensic services offered by the FBI Laboratory.

### **3.2 Environmental Health and Safety**

FBI Laboratory operations are performed in a safe manner and in accordance with the standards established by applicable regulatory agencies. The FBI Laboratory Safety Manual is prepared by the FBI Laboratory Health and Safety Group.

### **3.3 Accreditation**

The FBI Laboratory is accredited to the requirements of the applicable accrediting body(ies) and is committed to maintaining accreditation.

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<sup>1</sup> Laboratory activities at the FBI Laboratory refers to testing and sampling.

### 3.4 Security and Access

It is the policy of the FBI Laboratory that all personnel, evidence, DNA database samples, and case records are secure in the FBI Laboratory facilities. Access to an FBI Laboratory building is restricted to FBI Laboratory personnel, authorized non-FBI Laboratory personnel, and others when escorted by FBI Laboratory personnel.

**3.4.1** Due to security, classification issues, and the sensitivity of cases within the FBI Laboratory, the Laboratory Director does not allow any unauthorized personnel to have access to the laboratory areas for the purpose of viewing forensic examinations or DNA databasing.

## 4 General Requirements

### 4.1 Impartiality

**4.1.1** The FBI Laboratory performs and manages its laboratory activities in an impartial and structured manner.

**4.1.2** FBI Laboratory management is committed to impartiality.

**4.1.3** The FBI Laboratory has policies to ensure that all personnel are free from any undue pressures and influences that may negatively impact the quality of their work. FBI Laboratory personnel encountering situations or conditions that could affect their impartiality inform their Unit Chief and/or the Quality Manager. Additionally, FBI Laboratory personnel annually review and sign the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science*.

**4.1.3.1** FBI Laboratory management:

- a) is committed to good professional practice as demonstrated by the code of ethics described in the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science*.
- b) ensures the *Department of Justice Code of Professional Responsibility for the Practice of Forensic Science* is reviewed annually with FBI Laboratory personnel. A record of the review is maintained by each Supervisor, Unit Chief, and/or Executive Management, as appropriate. These reviews may be conducted and recorded during each employee's annual performance review.
- c) ensures appropriate actions are taken when necessary.

**4.1.4** The FBI Laboratory Deputy Assistant Director is the Laboratory Director when specified in the quality system. The FBI Laboratory is part of the FBI Science and Technology Branch, led by the FBI Executive Assistant Director for the Science and Technology Branch. This ensures the independence of the FBI Laboratory from the rest of the organization, including the investigative branches of the FBI. Risks to impartiality are identified on an ongoing basis as described by the FBI Ethics and Integrity Program Policy Directive and Policy Guide. Annual

training related to the topics covered by the policy is required for all FBI Laboratory personnel. Additional measures to allow for the assessment of risks to impartiality include the requirement for specific positions to complete an *OGE-450 Confidential Financial Disclosure Report* and *No Known Conflicts of Interest With Federal Duties Certification*, and when applicable, the requirement for personnel to complete the *Request To Engage In Outside Employment* (FD 331) prior to employment to ensure there is not a risk to impartiality.

**4.1.5** If a risk to impartiality is identified, FBI Laboratory personnel eliminate or minimize the risk.

## **4.2 Confidentiality**

**4.2.1** The FBI Laboratory is responsible for the management of all information obtained or created during the performance of laboratory activities and has policies and practices to protect confidential information. These policies and practices include guidance for protecting the electronic storage and transmission of *Laboratory Reports* as well as access to test data. The FBI has additional policies and procedures regarding security and records management. [See LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases, LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), LOM - Practices for the Security of Evidence Storage Rooms]

**4.2.2** FBI Laboratory personnel only share information on cases with individuals who have a need to know (e.g., contributors, case agents, intelligence partners, prosecutors).

**4.2.3** Information about a contributor received by the FBI Laboratory is kept confidential between the contributor and the FBI Laboratory. The FBI Laboratory keeps the source of the information confidential and is not shared with the contributor, unless agreed to by the source.

**4.2.4** FBI Laboratory personnel keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

## **5 Structural Requirements**

**5.1** The FBI is the principal investigative arm of the United States Department of Justice. The FBI Laboratory is in Quantico, Virginia, and Huntsville, Alabama.

**5.2** The Laboratory Director has overall responsibility for the FBI Laboratory and manages the Quantico, Virginia, and Huntsville, Alabama, facilities.

**5.2.1** The Laboratory Director's duties are defined in the FBI Deputy Assistant Director job description.

**5.3** The laboratory activities conducted by the FBI Laboratory are defined in its ANSI National Accreditation Board (ANAB) scope of accreditation and its American Association for Laboratory Accreditation (A2LA) scope of accreditation. Additionally, laboratory activities in cryptanalysis, illicit business records, and anthropology conform to FBI Laboratory quality system requirements.

**5.4** The FBI Laboratory provides forensic services to address a contributor's request or submission of evidence, and/or a request to search biometric databases, and/or confirm biometric database match. These laboratory activities are conducted in such a way as to conform to the requirements of the applicable accrediting body(ies). Personnel performing DNA analysis comply with the National DNA Index System (NDIS) Operational Procedures Manual, the Quality Assurance Standards for Forensic DNA Testing Laboratories, and/or the Quality Assurance Standards for DNA Databasing Laboratories, as appropriate. The FBI Laboratory quality system covers forensic examinations and DNA databasing conducted at the FBI Laboratory in Quantico, Virginia; Huntsville, Alabama; and at any other facility(ies) or site(s) where FBI Laboratory personnel perform forensic services.

**5.4.1** The FBI Laboratory conforms to the requirements in the current ANAB policy titled *Use of ANAB Accreditation Symbols and Claims of Accreditation Status*.

**5.4.2** The FBI Laboratory performs laboratory activities under the authority of 28 Code of Federal Regulations Section 0.85 Subsection G, which is available on the Government Publishing Office website ([www.govinfo.gov](http://www.govinfo.gov)).

**5.5** The FBI Laboratory:

- a) Organizational Chart shows the structure and the relationships between Executive Management, the Quality Manager, technical operations (i.e., caseworking and DNA databasing units), and support services. The FBI Laboratory's position in the FBI is shown in the FBI Organizational Chart.
- b) defines the responsibility, authority, and interrelationship of all FBI Laboratory personnel who manage, perform, or verify work affecting the results of laboratory activities for the quality system in QAM - Section 5.6, unit organizational charts, and/or appropriate quality system documents.
- c) has procedures to ensure the consistent application of its laboratory activities and the validity of the results.

**5.6** The FBI Laboratory provides its personnel the authority and resources needed to carry out their duties including the implementation, maintenance, and improvement of the quality system. FBI Laboratory personnel support and promote the quality system and its continual improvement of the system.

The Forensic Analysis Support Unit (FASU) Chief serves as the FBI Laboratory Quality Manager for Quantico, Virginia, and Huntsville, Alabama, facilities and has direct access to the Laboratory Director.

**FBI Laboratory Executive Management:**

- ensures conformance to requirements of the applicable accrediting body(ies).
- ensures the policies, practices, procedures, training manuals, and accompanying forms within the quality system are implemented and followed in the FBI Laboratory.
- ensures nonconformities are appropriately addressed and recorded.

**The Quality Manager:**

- ensures the implementation, maintenance, and improvement of the quality system.
- provides reports and/or updates, as necessary, to Laboratory management on the performance of the quality system and any need for improvement.

**Unit Chiefs:**

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed within their unit.
- ensure any controlled quality system documents used by personnel within their unit are reviewed annually and revised when necessary.
- ensure the appropriate Technical Leader(s) is consulted when necessary. This includes approval of technical procedures, deviations, and corrective actions.
- ensure all unit personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure all unit personnel receive appropriate continuing education.
- ensure approval for the selection and use of technical procedures within the unit; criteria establishment for technical procedure validation; and as necessary, review and update of technical procedures.
- stop, suspend, and resume operations in the discipline and/or category of testing under their authority, when appropriate.
- ensure the completeness of *Laboratory Reports* and supporting case records through technical and/or administrative reviews, as applicable.
- ensure nonconformities are appropriately addressed and recorded.

**Personnel designated as Technical Leaders:**

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed within their discipline and/or category of testing.
- ensure technical personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure approval for the selection and use of technical methods and procedures within the discipline and/or category of testing; criteria establishment for technical procedure validation; and as necessary, review and update of technical procedures.

- ensure the examinations conducted are technically sound for each discipline and/or category of testing.
- stop, suspend, and resume operations in a discipline and/or category of testing under their authority, when appropriate.
- ensure nonconformities are appropriately addressed and recorded.

Personnel designated as Training Program Managers:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed as applicable to the training program.
- coordinate training programs for their unit/discipline.

Supervisors:

- ensure conformance to requirements of the applicable accrediting body(ies).
- ensure the current policies, practices, procedures, training manuals, and accompanying forms are implemented and followed by their respective personnel.
- ensure their respective personnel receive necessary training and are qualified and authorized to perform their assigned work.
- ensure the completeness of *Laboratory Reports* and supporting case records through technical and/or administrative reviews, as applicable.
- ensure nonconformities are appropriately addressed and recorded.

FASU personnel:

- coordinate the continued development and revision of the quality system.
- assist units, disciplines, and/or categories of testing in the development of specific quality system documents.
- support proficiency test administration for each category of testing.
- conduct periodic quality system audits to provide management with the necessary confidence that established quality system policies, practices, procedures, and objectives are being met.
- provide guidance and direction to personnel regarding conformance to accreditation standards as well as any resulting nonconformities.
- ensure nonconformities are appropriately addressed and recorded.

Personnel designated as Quality Assurance (QA) Representatives:

- ensure conformance to requirements of the applicable accrediting body(ies).
- make recommendations for improving the quality system.
- participate in revising the QAM and LOM, as requested.
- attend an approved auditor training course within one year of being appointed to this role.
- provide assistance, as requested, in performing audits.
- ensure nonconformities are appropriately addressed and recorded.

**Examiners:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- support management, when necessary, by reviewing validation records, technical procedures, and deviation requests and conducting technical and/or administrative reviews.
- ensure nonconformities are appropriately addressed and recorded.

**Technicians, Technical Specialists, Forensic Photographers, and personnel who process film or conduct post-mortem imaging:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- advise examiners or other appropriate personnel of relevant case-related or DNA databasing issues.
- ensure nonconformities are appropriately addressed and recorded.

**Evidence Management Unit (EMU) Personnel:**

- ensure compliance with current policies, practices, procedures, training manuals, and accompanying forms.
- ensure evidence procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- ensure nonconformities are appropriately addressed and recorded.

**5.7 Laboratory management ensures:**

- a) communication occurs with FBI Laboratory personnel and contractors by email, meetings, or other means concerning the effectiveness of the quality system and the importance of meeting the contributors' and other requirements; and
- b) the integrity of the quality system is maintained when changes are planned and implemented.

## **6 Resource Requirements**

### **6.1 General**

The FBI Laboratory has available the personnel, facilities, equipment, and support systems necessary to manage and perform its laboratory activities.

## 6.2 Personnel

**6.2.1** FBI Laboratory personnel that could influence the laboratory activities act impartially, are competent, and work within the quality system.

**6.2.2** Management ensures that the competence requirements for each function influencing the results of laboratory activities<sup>2</sup>, including requirements for education, qualification, training, technical knowledge, skills, and experience are documented.

FBI Laboratory personnel meet the position requirements specified in the Individual Occupational Requirements in the Office of Personnel Management General Schedule Qualification Standards. Additionally, personnel influencing the results of laboratory activities meet the qualification, training, technical knowledge, skills, and experience requirements as defined by the applicable discipline(s)/category(ies) of testing training program.

**6.2.2.1** Personnel who authorize results, opinions, and/or interpretations meet the minimum educational requirements in the table below.

**Table 1.** Minimum Educational Requirements for Personnel who authorize results, opinions, and/or interpretations in the following disciplines

Discipline	Minimum Educational Requirements
Fire Debris and Explosives Geological Materials Gunshot Residue Materials (Trace) Seized Drugs Toxicology	A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.
Biology	A baccalaureate or an advanced degree in a chemical, physical, or biological science. If performing DNA analysis and where applicable, meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories or Quality Assurance Standards for DNA Databasing Laboratories, as appropriate.
Document Examination Fire and Explosion Investigation Firearms/Toolmarks Footwear/Tire Tread Friction Ridge Cryptology Illicit Business Records Anthropology	Meet the educational requirement(s) specified in the Individual Occupational Requirements in the Office of Personnel Management General Schedule Qualification Standards.

<sup>2</sup> ANAB GD 3152, ISO/IEC 17025:2017 and ANAB 3125 Matrix of Laboratory Tasks

**6.2.2.2** Each unit, discipline, and/or category of testing within the FBI Laboratory has a training program(s) for personnel influencing the results of laboratory activities coordinated by a training program manager (TPM). A TPM may cover more than one category of testing. The training program includes a training manual(s) that is used to develop a person's knowledge, skills, and abilities as required to perform forensic examinations and/or DNA databasing. The training manual must contain goals and objectives, expectations, topic areas, and a general outline of the training material. Knowledge of administrative practices and job duties must be tested and can be covered in conjunction with a subject-matter Oral Board exercise. Administrative subjects to be covered include, at a minimum, the Laboratory Division organizational structure and mission, the FBI Laboratory QAM, the LOM, and the Safety Manual. Examiner trainees will also follow the requirements of the LOM - Practices for the Forensic Examiner Training Program.

When an experienced examiner, technician, or technical specialist is entering the training program, the appropriate Technical Leader is responsible for assessing the person's previous training and ensuring it is adequate and recorded. Modification to the training plan may be appropriate and is recorded by the appropriate Technical Leader for approval by the trainee's Unit Chief. Each Unit Chief and appropriate Technical Leader ensures that, at a minimum, a trainee successfully demonstrates competence according to the requirements in the relevant discipline(s), category(ies) of testing, and/or a specific task(s) prior to conducting independent casework activities or DNA databasing. [Refer to QAM - Section 6.2.2]

Training programs for each function influencing the results of laboratory activities, to the extent necessary based on job function, include:

- a) knowledge, skills, and abilities needed to perform work;
- b) general knowledge of forensic science;
- c) the application of ethics in forensic science;
- d) where applicable, training in the criminal law, civil law, and testimony;
- e) provisions for retraining;
- f) provisions for maintenance of skills and expertise;
- g) criteria for acceptable performance.

**6.2.3** FBI Laboratory personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

**6.2.3.1** FBI Laboratory personnel who perform testing are competency tested. Testing includes the review and authorization of results and expressing an opinion or an interpretation. The competency test includes practical examination(s) that cover the spectrum of anticipated tasks related to the testing. The competency test intended results are achieved prior to performing the tasks on evidence or DNA databasing samples. Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.

FBI Laboratory personnel whose responsibility includes reporting examination results, demonstrate their competency by completing a competency test(s) that includes, at a minimum:

- a) Practical examinations that cover the spectrum of anticipated work to be performed;
- b) A written *FBI Laboratory Report* to demonstrate their ability to appropriately convey results and/or conclusions and their significance;
- c) A written or oral examination to assess their knowledge of the discipline, category of testing, or task being performed.

**6.2.3.2** All personnel who perform technical reviews of results or evaluate testimony satisfactorily demonstrate competency as specified in QAM - Section 6.2.3.1.

**6.2.4** FBI Laboratory management communicates to personnel their duties, responsibilities, and authorities.

**6.2.5** Each unit maintains records determining the competence requirements of its personnel. Each Unit Chief ensures the documentation of the selection of personnel in accordance with FBI Human Resource requirements. Training of personnel is described in QAM - Section 6.2.2 and training records are maintained in the appropriate unit. Each person performing casework and/or DNA databasing is accountable to only one immediate supervisor per category of testing. The authorization(s) of personnel is recorded as described in QAM-Section 6.2.6. Continued monitoring of competence of personnel can be found in the unit's proficiency test records, evaluation of testimony records, and through technical and administrative reviews of casework. For personnel no longer participating in proficiency testing, but who are authorized to perform other laboratory tasks as described in the ANAB GD 3152, continued competence is monitored each accreditation cycle by a review of continuing education of a technical nature, observation of the task, or by having another authorized person repeat the task. A record of the continued monitoring of competence is retained.

**6.2.6** Personnel are authorized to perform specific laboratory tasks, including but not limited to:

- a) development, modification, verification, and validation of methods and procedures;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) report, review, verification, and authorization of results;
- d) conducting technical reviews;
- e) evaluation of testimony.

A person's successful completion of a training program, a portion(s) of the training program, or training for a specific task(s) is recorded in a qualification and authorization Electronic Communication (EC) (FD-1057). An example qualification and authorization EC is found in Appendix A. At a minimum, the EC(s) includes:

- the person's name,
- the person's unit,
- the training program, specified portion(s) of the training program, or training for a specific task(s) that the person completed,

- the position (e.g., examiner, technician, technical specialist),
- the training requirements met, to include a reference to the appropriate manuals (e.g., Laboratory Quality Assurance Manual, Laboratory Operations Manual, and appropriate training manual),
- a reference to any previous qualification, if applicable,
- start and end dates of the training,
- where the training record is maintained,
- the discipline(s), category(ies) of testing, and/or a specific task(s) in which the person has been deemed competent,
- a statement that the person is qualified to perform specific laboratory activities
- authorization to perform specific laboratory tasks, including use of associated equipment,
- authorization to issue *Laboratory Reports*, including providing opinions and interpretations, if applicable,
- authorization to provide investigative lead, intelligence, or information products (i3), if applicable,
- any additional authorizations as described in the GD 3152.

Each qualification and authorization EC is approved by the Forensic Examiner Training Program Manager, appropriate Technical Leader(s), and the appropriate Unit Chief(s), at a minimum. The applicable Section Chief(s) are on the distribution list in Sentinel.

Upon approval of each EC by all required personnel, the person is qualified and authorized to perform forensic examinations, DNA databasing, and/or the specific task(s), including using associated equipment, and when applicable, to issue *Laboratory Reports* and/or i3 products, including providing opinions and interpretations, or *DNA Match Confirmation Letters*.

Units have additional authorization records. Authorizations not related to the completion of training are recorded in an EC in Sentinel or a person's unit. If a person is authorized to perform a specific laboratory activity following the completion of a training program or a portion(s) of the training program, the additional authorization should be stated in the qualification and authorization EC. Additional authorizations may be formatted following the requirements in Appendix A. The above requirements also apply to contractors.

**6.2.7** FBI Laboratory personnel completed a minimum of eight hours of continuing education each fiscal year. Management establishes objectives for the continuing education of personnel to meet the present and anticipated needs of the FBI Laboratory.

## **6.3 Facilities and Environmental Conditions**

**6.3.1** Units, disciplines, and/or categories of testing ensure facilities and environmental conditions are suitable for laboratory activities and do not adversely affect the validity of the results.

**6.3.2** Any environmental or facility conditions that can affect the results of examinations or DNA databasing are recorded in the appropriate technical procedure. Examinations and DNA databasing require typical laboratory environmental conditions unless noted in a technical procedure.

**6.3.3** If environmental conditions affect the quality of an examination or DNA databasing, the affected units, disciplines, and/or categories of testing will monitor, control, and record those conditions as required by a level 2 document. Examinations and DNA databasing are stopped when the environmental conditions jeopardize the results.

**6.3.4** Measures to control the FBI facilities where laboratory activities are performed are implemented, monitored and periodically reviewed and include, but are not limited to:

- a) access to and use of areas affecting laboratory activities;
- b) prevention of contamination, interference, or adverse influences on laboratory activities;
- c) effective separation between areas with incompatible laboratory activities.

**6.3.4.1** Redacted

**6.3.5** When laboratory activities are undertaken at sites or facilities other than a permanent FBI Laboratory facility, personnel ensure requirements related to facilities and environmental conditions are met.

## **6.4 Equipment**

**6.4.1** The FBI Laboratory is furnished with, or has access to, all items needed for the correct performance of laboratory activities and that can influence results.

**6.4.2** Units, disciplines, and/or categories of testing ensure that the function, maintenance, and/or calibration status of any piece of equipment outside the permanent control of the FBI Laboratory used for testing activities meets the requirements for equipment as stated in the QAM, LOM - Practices for the Calibration and Maintenance of Equipment, and applicable unit, discipline, and/or category of testing documents.

**6.4.3** Units, disciplines, and/or categories of testing have procedures for handling, transport, storage, use, and planned maintenance of equipment in order to ensure proper functioning, and to prevent contamination or deterioration.

**6.4.3.1** Units, disciplines, and/or categories of testing have procedures for checking the reliability of reagents. Reagents prepared in the FBI Laboratory are labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records maintained by the units, disciplines, and/or categories of testing identify who made the reagents and the components used in preparation.

**6.4.3.2** Units, disciplines, and/or categories of testing utilizing reference collections for identification, comparison, or interpretation purposes have each entry in the collection documented, uniquely identified, and handled properly to protect the characteristic(s) of interest.

**6.4.4** Equipment and its software used for the examination of evidence or DNA databasing must meet the requirements of the relevant technical procedure. Before being placed into or returned to service, equipment is calibrated and/or checked by the unit, discipline, and/or category of testing to verify that it meets the specifications. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.5** Unit, discipline, and/or category of testing personnel ensure the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.6** The FBI Laboratory requires that measuring equipment is calibrated as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.7** Units, disciplines, and/or categories of testing have a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

**6.4.7.1** The requirements for the program for the calibration of equipment are specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.8** FBI Laboratory equipment requiring calibration is labeled, coded or otherwise identified as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.9** Any equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements is taken out of service and the effect is determined as specified in the LOM - Practices for Calibration and Maintenance of Equipment.

**6.4.10** When intermediate checks are needed to maintain confidence in the performance of the equipment, these checks are carried out according to unit, discipline, and/or category of testing procedures. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.4.11** Calibration and reference material data including reference values or correction factors are handled according to the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.4.12** Units, disciplines, and/or categories of testing take practicable measures to prevent unintended adjustments of equipment from invalidating test results. [LOM - Practices for the Calibration and Maintenance of Equipment].

**6.4.13** Units, disciplines, and/or categories of testing maintain records of each piece of equipment and its associated software used for forensic examinations or DNA databasing according to the LOM - Practices for the Calibration and Maintenance of Equipment.

## **6.5 Metrological Traceability**

**6.5.1** Units, disciplines, and/or categories of testing establish and maintain metrological traceability of measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. [LOM - Practices for the Calibration and Maintenance of Equipment]

**6.5.1.1** The LOM - Practices for the Calibration and Maintenance of Equipment documents requirements for suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability.

**6.5.1.2** If a supplier of traceable materials or services is not available; Laboratory personnel follow the requirements in the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.5.1.3** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**6.5.1.4** Laboratory personnel refer to the LOM - Practices for the Calibration and Maintenance of Equipment for the requirements that are followed when a certified reference material is changed in a way that alters the traceable measurement value.

**6.5.2** Units, disciplines, and/or categories of testing ensure measurement results are traceable to the International System of Units (SI) according to the LOM - Practices for the Calibration and Maintenance of Equipment.

**6.5.3** When metrological traceability of measurements to SI units is not technically possible, metrological traceability to an appropriate reference is demonstrated according to the LOM - Practices for the Calibration and Maintenance of Equipment for information.

## **6.6 Externally Provided Products and Services**

**6.6.1** The FBI Laboratory selects suitable externally provided products<sup>3</sup> and services that affect laboratory activities when such products and services:

- a) are intended for incorporation into FBI Laboratory activities;

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<sup>3</sup> Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

- b) are provided, in part or in full, directly to the contributor by the FBI Laboratory, as received from the external provider; or
- c) are used to support the operation of the FBI Laboratory.

**6.6.2** The FBI Laboratory's procedure for using external providers is as follows:

- a) FBI Laboratory Unit Chiefs, Technical Leaders, and where applicable, FASU personnel, are responsible for evaluating the suitability of external providers who provide products and services affecting laboratory activities. Federal and FBI Finance and Facilities Division Procurement Policies and Regulations govern the procurement of products and services from sources external to the FBI. The Financial and Portfolio Management Unit ensures compliance with all Federal, FBI, and divisional budget/accounting policies. Units, disciplines, and/or categories of testing have procedures for the reception and storage of reagents and consumable materials necessary for forensic examinations or DNA databasing. FBI Laboratory units, disciplines, and/or categories of testing ensure purchase requests contain information describing the supplies and services ordered if they affect laboratory activities. These requests are reviewed and approved by the appropriate Unit Chief prior to ordering.
- b) For the purchase of products and services that affect laboratory activities, units, disciplines and/or categories of testing evaluate suppliers, maintain records of these evaluations and maintain a list identifying approved suppliers. Units, disciplines, and/or categories of testing evaluate these materials to ensure compliance with specifications defined in the appropriate technical procedure and/or purchase request. These materials are not used until their compliance is verified and units, disciplines, and/or categories of testing maintain records of steps taken to check conformance of these materials. When an issue with a product or service that affects laboratory activities is identified, the external provider is re-evaluated, and a record is maintained.
- c) Externally provided products and services conform to FBI Laboratory requirements before they are used or directly provided to the contributor.
- d) Actions are taken as necessary and recorded when evaluations, performance monitoring, and re-evaluations of external providers warrant.

**6.6.3** Units, disciplines, and/or categories of testing communicate their requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that the unit, discipline, and/or category of testing, or its contributor, intends to perform at the external provider's premises.

## **7 Process Requirements**

### **7.1 Review of Requests and Contracts**

#### **7.1.1 The FBI Laboratory ensures:**

- a) requirements are adequately defined, recorded, and understood. The Handbook of Forensic Services, the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission provide requirements for the review of requests for examinations and the contract that is entered into when a contributor submits evidence to the FBI Laboratory. The information obtained from the examination of Terrorist Explosive Device Analytical Center (TEDAC) evidence is shared with domestic and international partners. Additionally, the LOM - Practices for Assigning Cases and Conducting Examinations details the requirements for Laboratory acknowledgment of evidence receipt.
- b) it has the capability and resources to meet the requirements as stated above. Communication with contributors about the appropriateness of requested examinations is described in the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission.
- c) externally provided products and services conform to the Laboratory's established requirements. The appropriate Unit Chief and Technical Leader conduct reviews of requests on any work that is to be performed by an external provider. When external providers are used, the requirements of QAM - Section 6.6 are applied and the appropriate Unit Chief advises the contributor of the specific laboratory activities to be performed by the external provider and obtains the contributor's approval. When examinations are completed by partner laboratories, intelligence partners or are generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis and Racketeering Records Unit evidence), approval from the contributor is not required.
- d) the appropriate methods or procedures are selected and are capable of meeting the contributor's requirement(s) as described in the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission.

**7.1.2** FBI Laboratory personnel determine the appropriate technical processes to address the contributor's request for examination. [QAM - Section 7.1.1a]

**7.1.3** When the contributor requests a statement of conformity to a specification or standard for the test (e.g., pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the

decision rule<sup>4</sup> is clearly defined. Unless inherent in the requested specification or standard, the decision rule is communicated to, and agreed with, the contributor.

**7.1.4** The Handbook of Forensic Services, the LOM - Practices for Processing a Submission and Evidence Breakdown, the LOM - Practices for Assigning Cases and Conducting Examinations, and the LOM - Practices for Processing a Single Unit Submission provide requirements for the review of requests for examinations and the contract that is entered when a contributor submits evidence to the FBI Laboratory.

**7.1.5** Any deviations from a contributor's request, such as conducting additional examinations that were not requested, are communicated to the contributor by the examiner or the personnel initiating the change prior to laboratory activities commencing. This communication is recorded. The identification of an additional examination(s) not requested that may be probative and generally expected by a contributor (i.e., TEDAC evidence; chemical, biological, radiological and nuclear items; Cryptanalysis and Racketeering Records Unit evidence) are not communicated to the contributor.

**7.1.6** If any changes are made to an *Examination Plan*<sup>5</sup> (7-262) after work has commenced, the requirements of QAM - Section 7.1.1 are followed and the changes are communicated to all affected examiners by the person managing the case.

**7.1.7** The LOM - Practices for Assigning Cases and Conducting Examinations and the LOM - Practices for Processing a Single Unit Submission detail the requirements for personnel contacting and communicating with the contributor. [QAM - Section 7.7.1]

**7.1.8** An *Examination Plan* records the review of the incoming communication which details the request for examination(s) for submissions. Any significant changes to an *Examination Plan* are recorded by the person managing the case. In addition, the contributor is contacted about the submission, according to the LOM - Practices for Processing a Submission and Evidence Breakdown and the LOM - Practices for Assigning Cases and Conducting Examinations. The *Examination Plan* and record of communication with the contributor are included in the FBI Laboratory file. [LOM - Practices for Assigning Cases and Conducting Examinations]

**7.1.9** The extent of database searches is communicated to the contributor and updated, as needed, according to the LOM - Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases or the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Report and Retaining Records in Forensic Advantage (FA), as appropriate.

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<sup>4</sup> Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

<sup>5</sup> *Examination Plans* are not required for Single Unit Submissions based on evidence that meets the requirements of, and is handled as described in, the LOM – Processing a Single Unit Submission.

## **7.2 Selection, Verification and Validation of Methods**

### **7.2.1 Selection and Verification of Methods**

**7.2.1.1** FBI Laboratory units, disciplines, and/or categories of testing have and use procedures for all examinations and DNA databasing within their scope. Where appropriate, technical procedures include the estimation of the measurement uncertainty as well as statistical techniques for the analysis of examination and DNA database data.

**7.2.1.1.1** The FBI Laboratory uses appropriate methods and procedures for all associated data analysis and interpretation.

**7.2.1.1.2** If a technical procedure involves the comparison of an unknown to a known, the procedure requires the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s)<sup>6</sup>.

**7.2.1.1.3** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**7.2.1.2** Quality system documents relevant to laboratory activities are kept up to date and are readily available according to the LOM - Practices for Document Control.

**7.2.1.3** Units, disciplines, and/or categories of testing ensure they use the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

**7.2.1.4** Examiners select appropriate methods and procedures to meet the needs of the contributor while taking into account the nature of the evidence, the request for examination, and any pertinent case information received. The methods are published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, or are developed or modified by the FBI Laboratory.

**7.2.1.5** Unit, discipline and/or category of testing personnel verify that they can properly perform methods before introducing them by ensuring they can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary. [LOM - Practices for Developing Methods and Validating Technical Procedures]

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<sup>6</sup> This requirement is not focused on the process of assessing an unknown in order to identify evidence that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known sample prior to the assessment of the unknown.

**7.2.1.6** When unit, discipline, or category of testing personnel develop a method, it is a planned activity and is assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm the needs of the contributor are still being fulfilled. Any modifications to the development plan are reviewed and authorized. [LOM - Practices for Developing Methods and Validating Technical Procedures and LOM - Practices for Validating Chemical Procedures]

**7.2.1.7** Deviations from quality system requirements are recorded, justified, and authorized according to the LOM - Practices for Authorizing Deviations.

## **7.2.2 Validation of Methods**

**7.2.2.1** Appropriate validation studies are conducted on all new technical procedures, non-standard methods and standard methods used outside their intended scope or otherwise modified when used for the analysis of evidence. Validations for new technical procedures are performed according to the LOM - Practices for Developing Methods and Validating Technical Procedures and the LOM - Practices for Validating Chemical Procedures, as appropriate, to ensure the procedure produces reliable results.

**7.2.2.1.1** Requirements for the validation of technical procedures are found in the LOM - Practices for Developing Methods and Validating Technical Procedures and the LOM - Practices for Validating Chemical Procedures.

**7.2.2.2** When changes are made to a validated technical procedure, the influence of such changes is determined and where they are found to affect the original validation, a new validation is performed.

**7.2.2.3** The performance characteristics of validated technical procedures, as assessed for the intended use, are relevant to the contributor's needs and consistent with specific requirements.

**7.2.2.4** Units, disciplines, and/or categories of testing maintain records of the validation including:

- a) the procedure used;
- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- d) the results obtained;
- e) a statement on the validity of the method, detailing its fitness for intended use.

## **7.3 Sampling**

**7.3.1** Each unit, discipline, and/or category of testing, when they carry out sampling (i.e., selection of a sample for testing according to a procedure) has a sampling plan(s) and procedure which details how the sampling will occur. The approach to sampling can be non-statistical or statistical. Sampling plans are based on statistical methods when appropriate and address the

factors to be controlled to ensure the validity of the examination results. The sampling plan and procedure is available at the site where sampling is undertaken.

**7.3.2** The sampling procedure describes:

- a) the selection of samples or sites;
- b) the sampling plan;
  - 1. Statistical sampling at a stated level of confidence is used if an inference is made to report on the whole population.
- c) the preparation and treatment of a sample(s) from a substance, material, or product to conduct the appropriate examinations.

**7.3.3** Units, disciplines, and/or categories of testing, as applicable, record appropriate sampling data and activities relating to the examination. Records are maintained in the FBI Laboratory and include, where relevant:

- a) sampling procedure(s) used;
- b) date and time of sampling;
- c) data to identify and describe the sample;
- d) identification of the personnel performing the sampling;
- e) identification of the equipment used;
- f) environmental or transport conditions;
- g) diagrams or other equivalent means to identify the sampling location, when appropriate;
- h) deviations from the sampling procedure and sampling plan.

## **7.4 Handling of Items of Evidence**

**7.4.1** The FBI Laboratory maintains practices for the transportation, receipt, handling, protection, storage, retention, and disposal or return of items of evidence. These practices specify requirements for protecting the integrity of evidence, protecting the interests of the FBI Laboratory and its contributors. The FBI Laboratory ensures the integrity of evidence by protecting items from loss, cross-transfer, or deleterious change during storage, handling, and preparation for examination. Appropriate handling instructions provided with an item are followed. The DNA units maintain procedures for the transportation, receipt, handling, protection, storage, retention, and disposal of DNA databasing samples. [LOM - Practices for the Security of Evidence Storage Rooms, LOM - Practices for Processing a Submission and Evidence Breakdown, LOM - Practices for Assigning Cases and Conducting Examinations, LOM - Practices for Transferring and Storing Evidence, and LOM - Practices for Shipping and Returning Evidence]

**7.4.1.1** For all test items received except known origin individual characteristic database samples:

- a) the evidence is stored, packaged, and sealed according to the LOM - Practices for the Security of Evidence Storage Rooms, LOM - Practices for Processing a Submission and Evidence Breakdown, LOM - Practices for Assigning Cases

and Conducting Examinations, LOM - Practices for Transferring and Storing Evidence, and LOM - Practices for Shipping and Returning Evidence. Evidence is resealed as soon as practicable.

- b) the evidence is secured when unattended according to the LOM - Practices for Transferring and Storing Evidence. Level 2 quality manual documents define active examination for all evidence in the process of examination. The time period for active examination cannot be open-ended and is based upon a justifiable expectation of frequent examination.
- c) the evidence is recorded on a Chain-of-Custody Log according to the LOM - Practices for Transferring and Storing Evidence. Secondary evidence and subdivided items of evidence are tracked on the appropriate Chain-of-Custody Log. When evidence, such as latent prints and impressions, can only be recorded or collected by lifting, photography, or digital capture and the print or impression itself is not recoverable, the lift, photograph, negative or digital image of the print or impression is treated as evidence and tracked on the appropriate Chain-of-Custody Log.
- d) the evidence is securely and accurately identified on the appropriate Chain-of-Custody Log according to the LOM - Practices for Transferring and Storing Evidence.
- e) the disposition of that evidence requires communication to the contributor regarding disposition. [LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA)] and
- f) any items collected or created and preserved for future testing are addressed according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.4.2** The FBI Laboratory identifies all items of evidence according to the LOM - Practices for Processing a Submission and Evidence Breakdown, and the LOM - Practices for Assigning Cases and Conducting Examinations. Also, the FBI Laboratory General Description of Evidence provides additional guidance for the breakdown of evidence. The identification of evidence remains in place while the items are in the FBI Laboratory. These practices ensure that these items of evidence are uniquely identified and provide requirements for subdivided and secondary evidence. Evidentiary items are transferred within and from the FBI Laboratory according to the LOM - Practices for Transferring and Storing Evidence and the LOM - Practices for Shipping and Returning Evidence. Each item of evidence is marked to ensure it is uniquely identified and traceable to the FBI Laboratory number. If the evidence does not lend itself to marking, its proximal container or identifying tag is marked. The DNA units maintain procedures for the unambiguous identification of DNA databasing samples. [LOM - Practices for Processing a Submission and Evidence Breakdown and LOM - Practices for Assigning Cases and Conducting Examinations]

**7.4.2.1** Forensic Advantage (FA) is utilized to identify all evidence received. Refer to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases for Office of Professional Responsibility (OPR) investigations or prohibited cases.

**7.4.3** Upon receipt of the evidence, the condition of the evidence is evaluated and any conditions adverse to quality are recorded as described in the LOM - Practices for Processing a Submission and Evidence Breakdown. When the suitability of an item of evidence for examination is questionable, there is a discrepancy between the evidence and the request for examination, or the request for examination is unclear, the person managing the case, or the examiner will ensure the contributor is contacted for clarification prior to proceeding with any testing. This communication is recorded in a Case Record/Case Communication Log in FA or *Activity and Communication Log* (7-245) according to the LOM - Practices for Processing a Submission and Evidence Breakdown, and the LOM - Practices for Assigning Cases and Conducting Examinations. The DNA units maintain procedures for received DNA databasing samples that do not meet specified conditions and/or when there is a doubt about the suitability of a DNA database sample.

**7.4.4** When evidentiary items need to be stored or handled under specified environmental conditions, these conditions are maintained, monitored, and recorded. The LOM - Practices for the Handling Drug and Valuable Evidence describes how drug and valuable evidence are stored and handled.

## **7.5 Technical and Case Records**

**7.5.1** The FBI Laboratory retains technical records for each laboratory activity. These records contain adequate information to facilitate, if possible, the identification of factors affecting measurement uncertainty and to enable the examination to be repeated under conditions similar to that of the original examination. Technical records include the date and identity of personnel responsible for each laboratory activity. The FBI Laboratory also retains case records. Original observations, data, and calculations are recorded at the time they are made and are identifiable with the specific task. Records are generated and retained according to the LOM - Practices for Calibration and Maintenance of Equipment; LOM - Practices for Assigning Cases and Conducting Examinations; LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases; and LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). The DNA units maintain procedures for DNA *Match Confirmation Letters* and retaining technical records for DNA databasing.

Administrative records contain the FBI Laboratory number on each page of or on at least the first page of bound administrative records. For electronic administrative records, the FBI Laboratory number can be applied electronically. Examination records contain the FBI Laboratory number on each page, the starting and ending date(s) of the examinations, the examiner's initials and the initials of the person preparing the examination records when the records are produced by someone other than the examiner. The person's initials are on the page(s) of the examination

records representing their work. When data for multiple cases is included on one printout, each of the FBI Laboratory numbers represented will be recorded on the printout. When information is recorded on the front and back of an examination record, each side is identified as an individual page, signed or initialed, and labeled with the FBI Laboratory number. [LOM - Practices for Assigning Cases and Conducting Examinations].

**7.5.1.1** The FBI Laboratory retains all technical records. The LOM - Practices for Assigning Cases and Conducting Examinations, the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), the LOM - Practices for Preparing, Reviewing and Issuing Laboratory Reports and Retaining Records for Legacy Cases and level 2 documents identify what records are maintained in the FBI Laboratory file.

**7.5.1.2** Abbreviations and/or symbols specific to the unit, discipline, and/or category of testing are acceptable if they are clearly defined in a level 2 document.

**7.5.1.3** Technical records are such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data. [LOM - Practices for Assigning Cases and Conducting Examinations, LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), and LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases]

**7.5.1.4** Technical records and case records are of a permanent nature. Any exceptions to this are noted in the LOM - Practices for Assigning Cases and Conducting Examinations.

**7.5.1.5** If an observation, data, or calculation is rejected, the reason, the identity of the person taking the action and the date are recorded in the technical record.

**7.5.1.6** If an adjustment or repair is performed due to a calibration that does not meet specifications, pre- and post-adjustment/repair data is retained.

**7.5.2** Amendments to physical case records or DNA databasing records are made with an initialed single strike-out, date of the change, and the change entered alongside. Nothing in the case records or DNA databasing records is erased or otherwise made illegible. The Quality Manager must approve any alternate method for indicating changes to physical records, and it must be described in a level 2 document.

For electronic case records or DNA databasing records, sufficient information to determine what was amended, the date of the change, and who made the change is maintained (e.g., track changes, maintaining both the original and amended data and files). For electronic records, measures are taken to avoid loss or change of original data.

Contemporaneous changes (i.e., those made before reaching a decision point) are not considered amendments.

## 7.6 Evaluation of Measurement Uncertainty

**7.6.1** Units, disciplines and/or categories of testing identify the contributions to measurement uncertainty. These contributions are recorded in each appropriate technical procedure, or the appropriate technical procedure will reference the location of the record(s) of the identified contributions if the record(s) is retained elsewhere. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are taken into account using the appropriate methods of analysis.

**7.6.1.1** Technical procedures, when applicable, include considerations for estimating the measurement uncertainty. The method of analysis for evaluation of measurement uncertainty:

- a) requires the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
- b) includes the process of rounding the expanded uncertainty;
- c) requires the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
- d) specifies the schedule to review and/or recalculate the measurement uncertainty.

**7.6.2** The FBI Laboratory does not perform calibrations as part of its scope of accredited activities.

**7.6.3** Estimation of measurement uncertainty is based on an understanding of the theoretical principles or practical experience of the performance of the method. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method.

**7.6.3.1** Units, disciplines, and/or categories of testing evaluate or estimate measurement uncertainty when applicable, for all reported quantitative results.

**7.6.4** Unit, disciplines and/or categories of testing maintain the following records for each evaluation and estimation of measurement uncertainty:

- a) statement defining the measurand;
- b) statement of how traceability is established for the measurement;
- c) the equipment (e.g., measuring device(s) or instrument[s]) used;
- d) all uncertainty components considered;
- e) all uncertainty components of significance and how they were evaluated;
- f) data used to estimate repeatability, intermediate precision, and/or reproducibility;
- g) all calculations performed; and
- h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

## 7.7 Ensuring the Validity of Results

**7.7.1** Units, disciplines, and/or categories of testing have procedures for monitoring the validity of forensic examinations and DNA databasing. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the review of the results. Monitoring is planned and reviewed and will include the following, where appropriate:

- a) use of certified reference materials, secondary reference materials and/or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replication of tests using the same or different procedures;
- g) retesting of retained items;
  - 1. When a verification of a result is carried out, it is conducted by a person who is currently qualified and authorized to perform the testing; a record of the verification is made identifying who performed the verification, when it was performed, and the result of the verification. The resolution of any discrepancy is also recorded. [LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in FA; LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases; LOM - Practices for Resolution of Scientific or Technical Disagreement];
- h) correlation of results for different characteristics of an item of evidence;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s);
- l) technical review of examination records, including *Laboratory Reports*, and evaluation of testimony. These procedures are described in LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases, and LOM - Practices for Testimony Related Activities.

**7.7.2** The FBI Laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. The FBI Laboratory participates in proficiency testing. Proficiency testing applies to personnel who perform testing activities in each discipline and/or category of testing in which casework, or DNA databasing is performed.

**7.7.2.1** The FBI Laboratory's proficiency testing program is administered according to the LOM - Practices for Open Proficiency Testing.

**7.7.3** Data from monitoring activities is analyzed, used to control and, if applicable, improve the FBI Laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria; to prevent incorrect results from being reported.

**7.7.4** Personnel who perform testing activities complete proficiency testing according to LOM - Practices for Open Proficiency Testing.

**7.7.5** The FBI Laboratory proficiency testing program is documented in the LOM - Practices for Open Proficiency Testing. In addition, each unit, discipline and/or category of testing quality manual contains procedures for both internal and external proficiency testing, as appropriate.

**7.7.6** The FBI Laboratory proficiency testing plan is addressed in the LOM - Practices for Open Proficiency Testing.

**7.7.7** Proficiency testing requirements are addressed in the LOM - Practices for Open Proficiency Testing. To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b) the FBI Laboratory uses, where appropriate, proficiency test providers for each discipline that are accredited to ISO/IEC 17043 or by an accreditation body that is a signatory to the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement or Inter American Accreditation Cooperation Multilateral Recognition Arrangement. Additionally, the proficiency test providers have the applicable proficiency test on their scope of accreditation.

**7.7.8** The FBI Laboratory maintains proficiency testing records according to the LOM - Practices for Open Proficiency Testing.

## **7.8 Reporting of Results**

### **7.8.1 General**

**7.8.1.1** *Laboratory Reports* are issued according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). These practices ensure the *Laboratory Reports* have been reviewed and authorized prior to issuance. The DNA units have procedures for DNA *Match Confirmation Letters*. The use of i3 products in reporting is addressed in the LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3). Units, disciplines and/or categories of testing using i3 products will define the criteria in a level 2 document used to determine if results or information will be reported via a *Laboratory Report* or an i3 product and describe when a *Laboratory Report* must be issued

**7.8.1.1.1** The authorizer of results reviews the technical record and records the review according to the LOM - Practices for Assigning Cases and Conducting Examinations; LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in

Forensic Advantage (FA); and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases.

**7.8.1.2** FBI Laboratory personnel accurately, clearly, unambiguously, and objectively report the results of each examination according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases, the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3), and level 2 documents. *Laboratory Reports* include information regarding the work conducted and any information necessary for the interpretation of results. All issued *Laboratory Reports* are retained as technical records.

**7.8.1.2.1** The FBI Laboratory generates a written and/or electronic *Laboratory Report* or an i3 product for every request for examination.

**7.8.1.2.2** Results are reported according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases, the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA), and the LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3).

**7.8.1.2.3** The FBI Laboratory does not perform calibrations as part of its scope of accreditation.

**7.8.1.3** A simplified *Laboratory Report* is prepared to improve the contributor's ability to understand the report. The Handbook of Forensic Services provides the contract that is entered when a contributor submits evidence to the FBI Laboratory.

The Laboratory Director and Quality Manager must approve initiatives. The approval of an initiative is recorded in an EC. Any associated requirements for generating and/or retaining case records including reporting, are specified in a level 2 document.

Any information required by ISO/IEC 17025, ISO/IEC 17020, and ANAB AR 3125 not covered in a *Laboratory Report* or an i3 product is maintained in the FBI Laboratory.

**7.8.1.3.1** All *Laboratory Reports* are prepared in a simplified way. The *Laboratory Report* omits the following information:

- contact info for the contributor
- date of receipt of the evidence item
- statement that the results apply to the sample as received, when the FBI Laboratory does not perform the sampling (e.g., the sample is provided by the contributor)
- sampling information including the date of sampling, location of sampling, the sampling plan and method, environmental conditions during sampling, and information to evaluate measurement uncertainty for subsequent examination, when the FBI Laboratory does perform the sampling, unless needed for

- interpretation of the results
- date examinations were conducted
- statement that results relate to items examined
- additions to, deviations, or exclusions from examination methods
- identification of data provided by the contributor
- disclaimer when the information is supplied by the contributor and can affect the validity of results.

## **7.8.2 Content of *Laboratory Reports***

**7.8.2.1** Requirements for the content of a *Laboratory Report* are found in the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases; the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA); and level 2 documents.

### **7.8.2.2 Format of *Laboratory Reports***

A *Laboratory Report* is prepared according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA). The FBI Laboratory is responsible for all the information provided in a *Laboratory Report* except when information is provided by the contributor.

## **7.8.3 Specific Requirements for *Laboratory Reports***

**7.8.3.1** A *Laboratory Report* includes additional information when necessary for the interpretation of the examination results. Additional information is described in the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.3.1.1** If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, FBI Laboratory personnel have objective evidence of the regulation, statute, case law or other legal requirement and have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

**7.8.3.2** When the FBI Laboratory is responsible for the sampling activity; a simplified *Laboratory Report* can be prepared, or the *Laboratory Report* can include additional information regarding the sampling activity when it is necessary for the interpretation of the examination results (refer to QAM - Section 7.8.5).

## **7.8.4 Specific Requirements for Calibration Certificates**

The FBI Laboratory does not issue calibration certificates.

## 7.8.5 Reporting Sampling-Specific Requirements

When the FBI Laboratory is responsible for the sampling activity, personnel will retain the following information in the FBI Laboratory. The information may also be included in the *Laboratory Report*.

- a) the date of sampling;
- b) unique identification of the item or material sampled;
- c) the location of sampling, including any diagrams, sketches, or photographs;
- d) a reference to the sampling plan and sampling procedure;
  - 1. If statistical sampling is used, the *Laboratory Report* contains the confidence level and corresponding inference regarding the population;
- e) details of any environmental conditions during sampling that affect the interpretation of the results;
- f) information required to evaluate measurement uncertainty for subsequent examination.

## 7.8.6 Reporting Statements of Conformity

**7.8.6.1** When a statement of conformity to a specification or standard is provided in the *Laboratory Report*, units, disciplines, and/or categories of testing have procedures for recording the decision rule<sup>7</sup> employed. These procedures ensure the decision rule takes into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and describe how to apply the decision rule.

**7.8.6.2** The statement of conformity in the *Laboratory Report* will clearly identify:

- a) to which results the statement of conformity applies;
- b) which specifications, standards, or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard).

## 7.8.7 Reporting Opinions and Interpretations

**7.8.7.1** Qualified and authorized examiners provide opinions and interpretations, in *Laboratory Reports*, *DNA Match Confirmation Letters*, or i3 products, when applicable, and record the basis upon which the opinions and interpretations have been made.

**7.8.7.2** The opinions and interpretations in a *Laboratory Report* and/or an i3 product are based on the results obtained from the tested item(s). Opinions and interpretations are identified in *Laboratory Reports* according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for

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<sup>7</sup> A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

## Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.7.3** When opinions and interpretations are directly communicated by dialogue with the contributor, a record of the dialogue is retained in the appropriate communication log. The LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA) contain requirements for providing expedited results to a contributor.

## 7.8.8 Amendments to *Laboratory Reports*

**7.8.8.1** When an issued *Laboratory Report* needs to be changed, amended, or reissued, any change of information is clearly identified, and, where appropriate, the reason for the change is included in the follow up *Laboratory Report*. Alternatively, this information may be captured in a *Laboratory Report* for an open case record in the discipline and/or category of testing.

**7.8.8.2** Once a *Laboratory Report* has been issued, any amendments are made in the form of another *Laboratory Report* according to the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records for Legacy Cases and the LOM - Practices for Preparing, Reviewing, and Issuing Laboratory Reports and Retaining Records in Forensic Advantage (FA).

**7.8.8.3** A follow up *Laboratory Report* is uniquely identified and contains a reference to the original *Laboratory Report(s)*.

## 7.9 Complaints

**7.9.1** As part of the FBI Laboratory's commitment to provide reliable forensic examinations, personnel take appropriate steps to address valid complaints regarding their services. The FBI Laboratory's process to receive, evaluate, and make decisions on complaints, including complaints received in a *Customer Satisfaction Assessment* (FD-1000), is documented in QAM - Sections 7.9.3 through 7.9.7.

**7.9.2** The process for handling complaints is available to any interested party upon request. Upon receipt of a complaint, personnel notify their Unit Chief in writing. The Unit Chief confirms whether the complaint relates to laboratory activities that the FBI Laboratory is responsible for and, if so, investigates the complaint. The Unit Chief ensures other laboratory management is made aware of the complaint, as appropriate. The FBI Laboratory is responsible for all decisions at all levels of the process for handling complaints.

**7.9.3** When handling complaints, the FBI Laboratory:

- a) receives, validates, investigates and decides what actions are to be taken in response to the complaint. If the Unit Chief identifies the complaint as a nonconformity, the FBI Laboratory addresses the complaint as described in

the LOM - Practices for Addressing a Nonconformity.

- b) tracks and records complaints, including actions undertaken to resolve them. Records are maintained by the appropriate Unit Chief(s) of all complaints, any relevant investigations, and responses by the affected unit(s).
- c) ensures any appropriate action is taken.

**7.9.4** The appropriate Unit Chief is responsible for gathering and verifying all necessary information to validate the complaint.

**7.9.5** When practicable, the appropriate Unit Chief acknowledges receipt of the complaint, provides the complainant with progress reports, and provides the outcome.

**7.9.6** The outcomes to be communicated to the complainant are made by, or reviewed and approved by, personnel not involved in the original laboratory activities in question.

**7.9.7** When practicable, the appropriate Unit Chief gives formal notice of the end of the complaint handling to the complainant (i.e., stating that a given message is the final communication regarding the complaint).

## **7.10 Nonconforming Work**

**7.10.1** The QAM - Section 8.7 and the LOM - Practices for Addressing a Nonconformity are followed when any aspect of laboratory activities or results of the work do not conform to the quality system. These practices ensure:

- a) the responsibilities and authorities for the management of nonconforming work are defined;
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the FBI Laboratory;
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
- d) a decision is taken on the acceptability of the nonconforming work;
- e) where necessary, the contributor is notified and work is recalled;
- f) the responsibility for authorizing the resumption of work is defined.

**7.10.2** The FBI Laboratory retains records of nonconforming work and actions regarding nonconforming work.

**7.10.3** Where the evaluation indicates the nonconformity could recur or there is doubt about the conformity of the operations of the FBI Laboratory with its quality system, QAM - Section 8.7 and the LOM - Practices for Addressing a Nonconformity are followed.

## **7.11 Control of Data and Information Management**

**7.11.1** The FBI Laboratory has access to the data and information needed to perform laboratory activities.

**7.11.2** The FBI Laboratory's laboratory information management system(s) used for the collection, processing, recording, reporting, storage, or retrieval of data is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) before introduction. Whenever there are any changes, including software configuration or modifications to commercial off-the-shelf software, they are authorized, recorded, and validated before implementation.

**7.11.2.1** Units, disciplines, and/or categories of testing have a plan for the validation of computer software developed in-house and retain records of the validation.

**7.11.3** The laboratory information management system(s):

- a) is protected from unauthorized access;
- b) is safeguarded against tampering and loss;
- c) is operated in an environment that complies with provider or laboratory specifications;
- d) is maintained in such a manner that ensures the integrity of the data and information; and
- e) failures are recorded and appropriate immediate and corrective measures are taken.

**7.11.4** The laboratory information management system(s) is maintained at an FBI facility.

**7.11.5** The FBI Laboratory ensures instructions, manuals, and reference data relevant to the laboratory information management system(s) are readily available to personnel.

**7.11.6** Units, disciplines, and/or categories of testing ensure calculations and data transfers are checked in an appropriate and systematic manner<sup>8</sup>.

**7.11.6.1** Technical records indicate the check was performed and who performed the check. When possible, the check is not conducted by the person who performed the calculation(s) or data transfer(s)<sup>9</sup>.

## **8 Quality System Requirements**

### **8.1 Options**

**8.1.1** The FBI Laboratory has an established quality system that supports and demonstrates the consistent achievement of the requirements in ISO/IEC 17025, ISO/IEC 17020, and ANAB AR 3125 and assures the quality of laboratory results. The FBI Laboratory's quality system is in accordance with Option A of ISO/IEC 17025 and ISO/IEC 17020.

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<sup>8</sup> This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

<sup>9</sup> This check may be part of a technical review.

**8.1.2** The FBI Laboratory quality system addresses, at a minimum:

- management system documentation (see QAM - Section 8.2);
- control of management system documents (see QAM - Section 8.3);
- control of records (see QAM - Section 8.4);
- actions to address risks and opportunities (see QAM - Section 8.5);
- improvement (see QAM - Section 8.6);
- corrective actions (see QAM - Section 8.7);
- Preventive actions (see LOM – Practices for Preventive Action);
- Complaints (See QAM – Section 7.9);
- internal audits (see QAM - Section 8.8);
- management reviews (see QAM - Section 8.9).

## **8.2 Quality System Documentation**

**8.2.1** The FBI Laboratory quality system establishes, documents, and maintains policies and objectives for the fulfillment of the requirements of the applicable accrediting body(ies). The quality policies and objectives are acknowledged and implemented at all levels of the FBI Laboratory.

**8.2.1.1** The following words (to include forms of the same word) used in ISO/IEC 17025 and ISO/IEC 17020, the requirements issued by the accrediting bodies, and those in quality system documents require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

**8.2.2** The quality policies and objectives address the competence, impartiality and consistent operation of the FBI Laboratory.

The management of the FBI Laboratory is dedicated to good laboratory practice and to the quality of the forensic services provided to contributors. The quality system of the FBI Laboratory ensures functions are performed as intended and conform to the requirements of applicable accrediting body(ies). FBI Laboratory personnel are responsible for ensuring they understand and apply the quality system to their daily activities.

All quality system documents are reviewed annually and updated as necessary to continuously improve the effectiveness of the quality system. If conditions or situations having an adverse impact on the quality system are identified, appropriate changes are made and/or corrective actions are implemented.

The FBI Laboratory quality system goals and objectives are as follows:

- To ensure FBI Laboratory results provided to contributors and other laboratories are reliable and scientifically sound.
- To establish formal methods of quality assurance within the FBI Laboratory through the implementation of recognized standards for good laboratory practice.

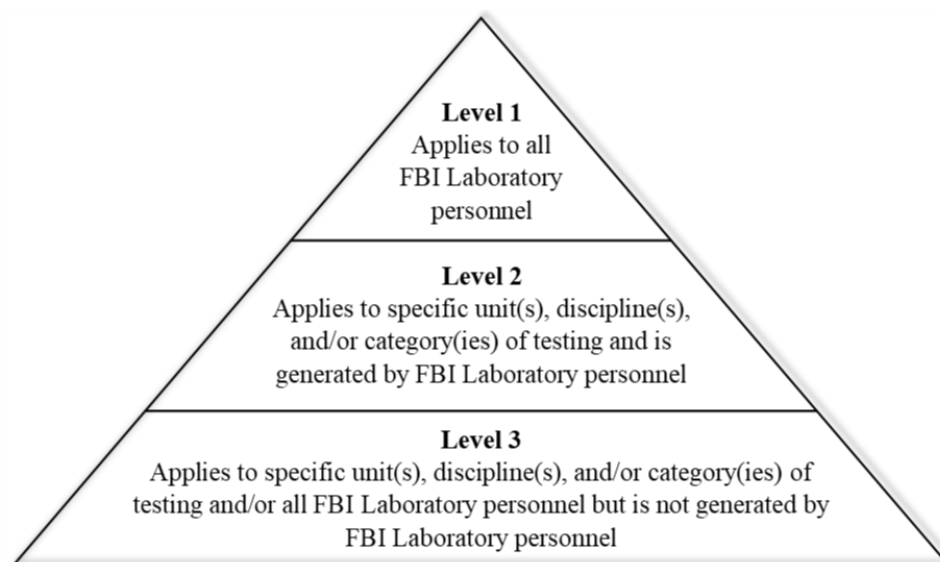
- To ensure procedures are valid, dependable, reproducible, and are adequate for the intended purpose.
- To ensure the routine operational performance of units within the FBI Laboratory are monitored.
- To ensure all areas of the quality system are periodically audited to demonstrate that policies, practices, and procedures are being followed and where applicable, accompanying forms are being used.
- To maintain quality, excellence, and integrity.
- To conform to the requirements of the applicable accrediting body(ies).
- To ensure necessary training is provided for personnel to carry out the provisions of the quality system.

**8.2.3** Management is committed to the development, implementation, and continuous improvement of the quality system. This is communicated via policies, the QAM and LOM, FBI Laboratory News emails, targeted issue emails, and meetings with FBI Laboratory personnel. With the support of the FBI Laboratory's management and input from personnel, new policies, practices, and procedures are developed, revised, and implemented when necessary.

#### **8.2.4 Document Hierarchy**

The FBI Laboratory's quality system is comprised of the QAM, LOM, quality manuals, technical procedures, non-technical procedures, FBI Approved Standards for Scientific Testimony and Report Language (ASSTR) and report writing procedures, training manuals, accompanying forms, and controlled equipment manuals as described in LOM - Practices for Document Control. Within the quality system, a document that applies to the entire FBI Laboratory is referred to as a level 1 document. A document that applies to a specific unit(s), discipline(s), and/or category(ies) of testing is referred to as a level 2 document. A level 3 document applies to a specific unit(s), discipline(s), and/or category(ies) of testing, but does not require approval by the Quality Manager.

The QAM provides requirements to meet the standards of the applicable accrediting body(ies) and other requirements based on the needs of the FBI Laboratory. FBI Laboratory practices and accompanying forms are found in the LOM. Practices are used to implement FBI Laboratory requirements defined in the QAM. The QAM and LOM are supplemented by quality manuals, technical procedures, training manuals, and accompanying forms. Technical procedures cover all relevant examinations and DNA databasing conducted by the FBI Laboratory. Training manuals cover appropriate training requirements for personnel responsible for receiving and breaking down evidence and performing laboratory tasks. Additionally, appropriate controlled equipment manuals are available to refer to for equipment used in examinations and DNA databasing, when necessary.



**Figure 1: FBI Quality System Document Hierarchy**

**8.2.5** All personnel involved in laboratory activities have access to the quality system documents and related information necessary for their responsibilities.

### **8.3 Control of Quality System Documents**

**8.3.1** The documents that comprise the FBI Laboratory quality system are controlled according to the LOM - Practices for Document Control. The official versions of the QAM, LOM, quality manuals, technical procedures, training manuals, and accompanying forms are posted on BUNET, LABNET and UNET.

**8.3.2** The LOM - Practices for Document Control ensures:

- a) all FBI Laboratory quality system documents are approved for adequacy prior to issuance by authorized personnel.
- b) documents are annually reviewed and revised, as necessary.
- c) changes in FBI Laboratory prepared quality system documents are identified and the current revision status of documents is identified.
- d) current versions of FBI Laboratory prepared quality system documents are available at points of use and their distribution is controlled, where necessary.
- e) quality system documents are uniquely identified.
- f) invalid and/or obsolete documents are promptly removed, archived and marked appropriately to preclude their use.

### **8.4 Control of Records**

**8.4.1** The FBI Laboratory retains legible records to demonstrate fulfillment of the requirements of the quality system.

**8.4.2** The FBI and FBI Laboratory have policies, practices, and procedures for the identification, access, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records.

## **8.5 Actions to Address Risks and Opportunities**

**8.5.1** The FBI Laboratory considers the risks and opportunities associated with laboratory activities in order to:

- a) give assurance that the quality system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the FBI Laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in laboratory activities; and
- d) achieve improvement of the quality system.

**8.5.1.1** The FBI Laboratory considers risks and opportunities related to health and safety through the Health and Safety Program.

**8.5.2** The FBI Laboratory plan includes:

- a) determination of risk associated with detected nonconformities;
- b) opportunities for improvement;
- c) the review of quality system documents, at a minimum on an annual basis, and revisions when needed. Reviews and revisions consider risks and opportunities for improvement;
- d) consideration of the risks and merits of requested deviations;
- e) a comprehensive evaluation of quality system activities, including the effectiveness of these actions, during the Annual Management Review of the quality system. The Annual Management Review determines the plan for improvement of the quality system in the coming year.

**8.5.3** FBI Laboratory management ensures actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

## **8.6 Improvement**

**8.6.1** FBI Laboratory personnel identify opportunities for improvement and implement any necessary actions.

**8.6.2** The FBI Laboratory encourages feedback from its contributors according to the LOM - Practices for Customer Satisfaction Assessments of FBI Laboratory Services. The feedback is analyzed and used to improve the quality system, laboratory activities, and customer service.

## **8.7 Corrective Actions**

**8.7.1** Any FBI Laboratory personnel may identify a situation or condition where a concession, correction, or corrective action is required. The LOM - Practices for Addressing a Nonconformity describes how the FBI Laboratory:

- a) reacts to the nonconformity and, as applicable, takes action to control and correct it, and addresses the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere by reviewing and analyzing the nonconformity, determining the cause(s) of the nonconformity, and determining if similar nonconformities exist or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) establishes a reasonable timeframe for completion.

The FBI Laboratory updates risks and opportunities determined during the Annual Management Review and makes changes to the quality system, if necessary. [QAM - Section 8.5.2]

**8.7.2** FBI Laboratory personnel ensure the response to a nonconformity is appropriate to the effect of the nonconformity encountered according to The LOM - Practices for Addressing a Nonconformity.

**8.7.3** The LOM - Practices for Addressing a Nonconformity describes the records that are generated and/or retained with respect to nonconformities.

## **8.8 Internal Audits**

**8.8.1** The LOM - Practices for Internal Audits are followed when conducting scheduled audits to verify that operations conform to the requirements of the FBI Laboratory quality system and the ISO/IEC 17025, ANAB AR 3125, and/or ISO/IEC 17020 requirements, as applicable. Audits are performed to provide information on whether the quality system is effectively implemented and maintained.

**8.8.1.1** Internal audits are conducted, at a minimum, on an annual basis according to the LOM - Practices for Internal Audits.

**8.8.2** The FBI Laboratory plans, establishes, implements, and maintains an audit program as described in the LOM - Practices for Internal Audits.

## **8.9 Management Reviews**

**8.9.1** The FBI Laboratory Executive Management and Quality Manager evaluate the quality system and laboratory activities to ensure their continued suitability, accuracy and effectiveness; additionally, the quality policies and objectives are reviewed. This management

review is used as the foundation for future development of FBI Laboratory goals and objectives as well as any necessary changes or improvements to the quality system.

**8.9.1.1** Management reviews are conducted on an annual basis.

**8.9.2** The management review inputs are recorded and assess:

- a) changes in internal and external issues relevant to the FBI Laboratory;
- b) fulfillment of objectives;
- c) the suitability, adequacy, and completeness of quality system documents for meeting the quality objectives of the FBI Laboratory and ISO/IEC 17025 and ISO/IEC 17020 standards, as applicable;
- d) status of actions from previous management reviews;
- e) outcome of any recent internal audits;
- f) corrective and preventive actions, including their status;
- g) external audits and/or assessments;
- h) changes in the volume and type of work being performed or in the range of laboratory activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of the organizational structure, personnel training, and resources to implement the FBI Laboratory quality system and fulfill its objectives;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

**8.9.3** Records of management reviews are serialized in Sentinel and record all decisions and actions related to:

- a) the effectiveness of the quality system and its processes;
- b) improvement of the laboratory activities related to the fulfillment of the accrediting bodies' requirements;
- c) provision of required resources;
- d) any issues identified and actions taken to address them. Laboratory management and the Quality Manager will ensure the actions are carried out within an appropriate and agreed upon timescale.

## 9 References

Code of Federal Regulations, Government Publishing Office, [www.gpo.gov](http://www.gpo.gov).

Corporate Policy Directives, FBI, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Safety Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

GD 3152, ISO/IEC 17025:2017 and ANAB AR 3125 Matrix of Laboratory Tasks, ANAB, Milwaukee, WI, November 28, 2018.

Handbook of Forensic Services, Federal Bureau of Investigation, Laboratory Division, latest revision. [www.fbi.gov](http://www.fbi.gov).

International Vocabulary of Basic and General Terms in Metrology, International Organization for Standardization, Geneva, Switzerland, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17020 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection, International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, July 1, 2020.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, July 1, 2020.

[www.anab.org](http://www.anab.org) for policies and guidance.

[www.a2la.org](http://www.a2la.org) for policies and guidance.

Rev. #	Issue Date	History
13	06/03/19	Entire document revised to conform to new accreditation requirements.
14	12/21/20	<p>Grammatical and formatting changes throughout</p> <p>1 - Updated introduction</p> <p>2 - Removed: 7-273 and 7-273 LIMS; Added: providing instrument operations support; Added: in legal proceedings</p> <p>3.1 - Removed: on a national and international level; Removed: and is available on BUNET, LABNET, various FBI networks, and the internet.</p> <p>3.2 - Removed: is available on BUNET and LABNET and various FBI networks.</p> <p>3.3 - Combined sentences</p> <p>3.4 - Changed person to personnel</p> <p>3.4.1 - Removed: the integrity of evidence is of utmost importance</p> <p>4.1.1 - Removed: to ensure impartiality</p> <p>4.1.3 - Removed: of their laboratory activities; Removed: American National Standards Institute (ANSI) National Accreditation Board (ANAB) Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists</p> <p>4.1.3.1 - Added: to good professional practice as demonstrated by the code of ethics described in; Removed: to the ANAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists</p> <p>4.1.4 - Defined Laboratory Director; Added: identified on an ongoing basis; Added: specific positions to complete an OGE-450 Confidential Financial Disclosure Report and No Known Conflicts of Interest With Federal Duties Certification; Added: Request To Engage In Outside Employment (FD 331)</p> <p>4.2.1 - Removed: contributors'; Removed: in examination areas</p> <p>4.2.2 - Added: intelligence partners</p> <p>4.2.4 - Added: confidential</p> <p>5.2 - Consolidated section</p> <p>5.3 - Added: ANSI National Accreditation Board; Replaced documents with requirements; Updated language to: address a contributor's request or submission of evidence, and/or a request to search biometric databases, and/or confirm biometric database match</p> <p>5.4 - Updated language to clarify who services provided to</p> <p>5.5 - Removed: The Laboratory Director manages the Quantico, Virginia and Huntsville, Alabama facilities; Added: organizational charts</p> <p>5.6 - Training Program Managers: Replaced discipline/category of testing with unit/discipline; Supervisors: Replaced unit personnel with respective personnel; Replaced Quality Assurance Specialists</p>

with FASU personnel;

6.2.1 - Reworded section

6.2.2 - Removed: including education

6.2.2.1 - Table 1: Updated discipline list

6.2.2.2 - Added: influencing the results of laboratory activities

6.2.3.1 - Replaced staff with personnel

6.2.5 - Added as described in the ANAB GD 3152

6.2.6 - Replaced alternately reported with investigative lead, intelligence, or information products (i3); Added any additional authorizations as described in the GD 3152; Added at a minimum; Added applicable: replaced alternately reported results with i3 products; Added an EC

6.2.7 - Replaced obtain with completed

6.3.4.1 - Removed Security Reference Guide for Laboratory Division Personnel

6.4.5 - Added personnel

7.1.1 - a) Removed to meet TEDAC's mission; b) Added as stated above

7.1.5 - Removed EMU

7.1.6 - Removed TEDAC Examination Plan (7-274); Replaced EMU personnel with person managing the case

7.1.8 - Removed TEDAC Examination Plan; Replaced EMU personnel with person managing the case

7.1.9 - Updated reference titles

7.2.1.5 - Added: personnel; Removed: that the FBI Laboratory

7.2.1.6 - Added: personnel

7.3.1 - Replaced sampling procedures with procedure which details how the sampling will occur; Removed: included in the appropriate SOP

7.4.1 - Replaced the interests of the contributor with its contributors

7.4.1.1 b) - Replaced. Unit, discipline, and/or category of testing with level 2; Added: documents

7.4.2 - Added: Also, the FBI Laboratory General Description of Evidence provides additional guidance for the breakdown of the evidence

7.4.2.1 - Removed reference to LOM - Practices for Processing a Submission and Evidence Breakdown

7.4.3 - Replaced EMU personnel with person managing the case; Replaced contact the contributor with ensure the contributor is contacted

7.5.1 - Reworded section

7.5.2 - Replaced changes with amendments; Replaced changed with amended; Added: The Quality Manager must approve any alternate method for indicating changes to physical records, and it

must be described in a level 2 document.

7.6.1 - Added: These contributions are recorded in each appropriate technical procedure, or the appropriate technical procedure will reference the location of the record(s) of the identified contributions if the record(s) is retained elsewhere.

7.6.4 - Added: estimation of

7.7.5 - Added: each unit, discipline and/or category of testing

7.7.7 - Added: where appropriate

7.8.1.1 - Added: The use of i3 products in reporting is addressed in the LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3). Units, disciplines and/or categories of testing using i3 products will define the criteria in a level 2 document used to determine if results or information will be reported via a Laboratory Report or an i3 product and describe when a Laboratory Report must be issued

7.8.1.2 - Updated reference titles; Added: LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3)

7.8.1.2.1 - Replaced alternate reporting product with i3 product

7.8.1.2.2 - Updated reference titles; Added: LOM - Practices for Providing Investigative Lead, Intelligence, or Information Products (i3)

7.8.1.3 - Reworded section; Removed: Alternately reported results undergo the same reviews as a Laboratory Report; Added: ISO/IEC 17020; Added: i3 product

7.8.1.3.1 - Added: unless needed for interpretation of the results

7.8.3.2 - Replaced sampling or sample selection with sampling activity

7.8.5 - Replaced sampling with sampling activity

7.8.7.1 - Added: or i3 products

7.8.7.1 - Replaced alternately reported results with an i3 product

7.8.8.1 - Replaced amended, supplemental, or superseding with follow up; Added: Alternatively, this information may be captured in a Laboratory Report for an open case record in the discipline and/or category of testing

7.8.8.2 - Removed: or supplements

7.8.8.3 - Replaced amended, supplemental, or superseding with follow up

7.9.3 a) - Replaced determines with identifies

7.11.2 - Removed: by the FBI Laboratory

8.1.1 - Added: ISO/IEC 17020

8.1.2 - Added: Preventive actions (see LOM – Practices for Preventive Action); Added: Complaints (See QAM – Section 7.9);

8.2.1.1 - Added: ISO/IEC 17020

8.2.4 - Added: FBI Approved Standards for Scientific Testimony

and Report Language (ASSTR) and report writing procedures;

Reworded to remove examples; Updated Figure 1;

8.3.1 - Added: UNET

8.4.1 - Reworded section for clarity

8.9.1 - Removed: in conjunction with

8.9.2 1) - Replaced staff with personnel

8.9.3 - Corrected list lettering

9 - Updated DNA QAS references; Removed Security Reference

Guide for Laboratory Division Personnel

Appendix A Updated

**Approval**

Redacted - Signatures on File

Laboratory Director

Date: 12/18/2020

Quality Manager

Date: 12/18/2020

## **Appendix A: Example Language to use in a Forensic Examiner, Technician, or a Specific Task(s) Qualification and Authorization EC**

The following provides guidance for preparing a Qualification/Authorization EC. The information in *italics* must be included in the Qualification/Authorization EC for FBI Laboratory personnel. There is also example language provided for each required heading (**in bold**). Language can be modified to cover whether the person has completed the entire training program for a discipline/category(ies) of testing, is being authorized to perform a specific task(s) as described in the ANAB GD3152, and/or was previously qualified and authorized and being re-qualified and authorized in same and/or new discipline/category(ies) of testing. For questions about the EC requirements, contact the Forensic Examiner Training Program Manager or the Quality Manager.

**Case ID#:** *Refer to Forensic Examiner Training Program Manager for the file number*

**Title:** *Provide a brief title that appropriately reflects:*

- *The training the person has completed (e.g., entire training program, specific task(s)).*
- *Include “Qualification” and “Authorization” as well as the person’s name in the title.*

**Title Example language:**

Completion of Forensic Examiner training for Forensic Examiner (Full Name), Qualification, and Authorization

**Synopsis:** *Briefly describe:*

- *The training the person has successfully completed (e.g., entire training program, specific task(s)).*
- *Include the person’s name, unit, and the official date of the training completion.*

**Synopsis Example language:**

To record (Examiner’s Full Name) successful completion of the Forensic Examiner Training Program in the (Unit) on (insert official date of training completion).

**Details:** *Describe in detail:*

- The training requirements the person has met, to include referencing the appropriate manuals.*
- Reference any previous qualification file number for a person in cases of re-qualification or additional qualifications.*
- Include the training period beginning and end dates.*
- State where the training record will be maintained.*
- State that the person is qualified and authorized as an FBI Examiner, Technician, and/or in a specific task(s) and in what unit.*
- State that the person is qualified and authorized to conduct work in a specific discipline/category(ies) of testing, and/or specific task(s), and where applicable, add applicable*

*authorizations as described in the ANAB GD3152. When referring to the discipline, also specify the category(ies) of testing where appropriate.*

Details Example language:

(Individual's Full Name) has successfully completed all training requirements as outlined in the Laboratory Quality Assurance Manual, Laboratory Operations Manual, and (Title) Training Manual. The training period began on (date) and was completed on (date). A complete record of (Individual's name) training is on file in the (Unit). Upon approval of this EC, (Individual's name) is recognized as a qualified and authorized FBI (title) in the (Unit). (Individual's name) is authorized to perform (examinations in the (specify the discipline(s)/category(ies) of testing as stated on Scope of Accreditation, or the specific tasks)), operate all associated equipment as defined by (Unit), (and when applicable, issue FBI *Laboratory Reports* including providing opinions and interpretations).

*The final sentence is only needed for personnel that have completed training as a Forensic Examiner. If personnel will provide i3 products, the final sentence will include that authorization. If personnel will be authorized to conduct any of the other tasks as described in the ANAB GD3152 following other requirements, a separate authorization EC will be generated.*